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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,936	11/20/2003	Tod R. Smeal	034536-0220	6791

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EXAMINER

AEDER, SEAN E

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,936	Applicant(s) SMEAL ET AL.	
	Examiner Sean E. Aeder, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to a method for monitoring the effect of a therapeutic composition on a mammal, classified in class 435, subclass 4.
- II. Claims 26-33, and 40-42, drawn to a method for selecting a mammal amenable to treatment with a PAK activity modulator comprising comparing the level of phosphorylated PAK in a test biopsy with the level of phosphorylated PAK in a control biopsy, classified in class 435, subclass 7.1.
- III. Claims 34-39 and 43-46, drawn to drawn to a method for selecting a mammal amenable to treatment with a PAK activity modulator comprising comparing the ratio of phosphorylated PAK to total PAK4 in a test biopsy to the ratio of phosphorylated PAK to total PAK4 in a control biopsy, classified in class 435, subclass 7.1.
- IV. Claims 47-48, drawn to a method for determining the level of phosphorylated PAK in a mammalian biopsy, classified in class 435, subclass 7.1.

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- V. Claims 49-50, drawn to a phosphospecific antibody raised against serine 474 or a PAK4 peptide, classified in class 530, subclass 387.1.
- VI. Claims 51-55, drawn to a method of identifying a compound that modulates PAK phosphorylation, classified in class 435, subclass 7.1.
- VII. Claims 56-61, drawn to a method for selecting a mammal amenable to treatment with a PAK activity modulator comprising determining whether PAK4 protein is overexpressed in a biopsy from a mammal, classified in class 435, subclass 7.1.
- VIII. Claims 62, drawn to drawn to a method for selecting a mammal amenable to treatment with a PAK activity modulator comprising determining whether PAK4 mRNA is overexpressed in a biopsy, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The invention of group V is a distinct product, while the inventions of groups I-IX are materially distinct methods. Group I is drawn to a method for monitoring the effect of a therapeutic composition, group II is drawn to a method for selecting a mammal comprising comparing the level of phosphorylated PAK in a test biopsy with the level of

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phosphorylated PAK in a control biopsy, group III is drawn to a method for selecting a mammal comprising comparing the ratio of phosphorylated PAK to total PAK4 in a test biopsy to the ratio of phosphorylated PAK to total PAK4 in a control biopsy, group IV is drawn to a method for determining the level of phosphorylated PAK in a mammalian biopsy, group VI is drawn to a method of identifying a compound that modulates PAK phosphorylation, VII is drawn to a method of selecting a mammal comprising determining whether PAK4 protein is overexpressed in a biopsy, and group VIII is drawn to a method for selecting a mammal comprising determining whether PAK4 mRNA is overexpressed in a biopsy. These methods differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used in the materially different process of inhibiting PAK activity.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species

Claims 2, 3, 6, 10, 12, 27, 28, 31, and 32 are generic to a plurality of disclosed patentably distinct species comprising the following: **mammals** (claims 2-3, 27-28), **cancers** (claim 6), **tissues** (claim 10, 31-32), and **fluids** (claim 12). The above species represent separate and distinct animals, cell types, or other types of products with different structures and functions such that one species could not be interchanged with

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the other. As such, each species would require different searches and the consideration of different patentability issues. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA



**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**